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Dykema Docket No. 065379-0053

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant:	Joerg ROSENBERG et al.	)	Examiner:	Jennifer Y. CHO
Serial No.:	10/539,505	)	Group Art Unit:	1621
Filed:	December 16, 2003	)	Confirmation No.:	4705
For:	Formulation Comprising Fenofibric Acid,	)		
	A Physiologically Acceptable Salt or	)		
	Derivative Thereof	)		

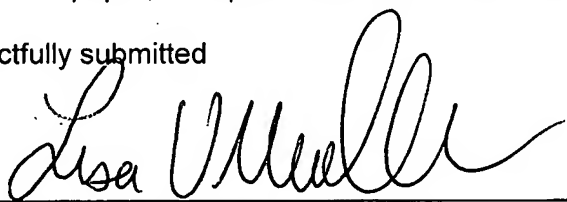
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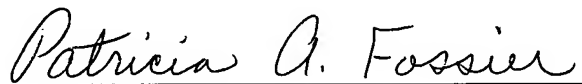
Respectfully submitted

By   
Lisa V. Mueller, Reg. No. 38,978

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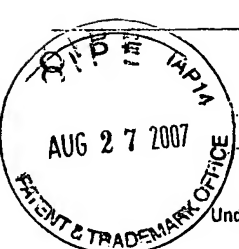
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06/28/2007 00000018 042223 10539505  
01 FC:1606 180.00 DA



PTO/SB/08a (08-03)

Approved for use through 07/31/2008. OMB 0651-0031  
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10539505
Filing Date	2003-12-16
First Named Inventor	Rosenberg, et al.
Art Unit	1621
Examiner Name	Jennifer Y. Cho
Attorney Docket Number	065379-0053

**U.S. PATENTS**

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	5179097		1993-01-12	Angres, Isaac	
	2	4160020		1979-07-03	Alza Corporation	
	3	4340585		1982-07-20	Alfa Farmaceutici, S.p.A.	
	4	4233298		1980-11-11	Orchimed S.A.	
	5	4800079		1989-01-24	Boyer, Jean-Francois	
	6	6284803		2001-09-04	BASF Aktiengesellschaft	
	7	4859703		1989-08-22	Warner-Lambert Company	
	8	4372954		1983-02-08	Moreau, Pierre et al.	

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9	4235896		1980-11-25	Orchimed S.A.	
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11	4072705		1978-02-07	Orchimed S.A.	
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30	3916899		1974-11-04	Alza Corporation	

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	31	2799241		1957-07-16	Wisconsin Alumni Research Foundation	
	32	4803081		1989-02-07	Aktiebolaget Hassle	
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	34	6514531		2003-02-04	Sanofi-Synthelabo	

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#### U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20010006662		2001-07-05	Krill, Steven et al.	
	2	20030077297	A1	2003-04-24	Chen, Feng-Jing, et al.	
	3	20050008704		2005-01-13	Ray, et al.	
	4	20050101561		2005-05-12	Tunac, et al.	
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	7	20050008704		2005-01-13	Ray, et al.	
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#### FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup>	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	474039	ES		1979-05-01			<input type="checkbox"/>
	2	2494112	FR		1982-05-21	Laruelle, Claude		<input type="checkbox"/>
	3	0173293	EP	B1	1991-10-30	Merrell Dow Pharmaceuticals Inc.		<input type="checkbox"/>
	4	01/03693	WO	A1	2001-01-18	Laboratoires Des Produits Ethiques Ethypharm		<input type="checkbox"/>
	5	02/11699	WO	A1	2002-02-14	IMPAX Laboratories, Inc.		<input type="checkbox"/>
	6	2004/054568	WO	A1	2001-07-01	Abbott GMBH & Co. Kg		<input type="checkbox"/>

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7	1415295	GB	1975-11-26	Mieville, Andre	<input type="checkbox"/>
8	1570488	GB	1980-07-02	Brisson, Henri, et al.	<input type="checkbox"/>
9	98/05331	WO	1998-02-12	Ligand Pharmaceuticals Incorporated	<input type="checkbox"/>
10	2004028506	WO	2004-04-08		<input type="checkbox"/>

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	International Conference on Harmonisation; Guideline for the Photostability Testing of New Drug substances and Products; Availability, Federal Register, Part II, Department of Health and Human Services, May 16, 1997, 27115-22, Vol. 62, No. 95	<input type="checkbox"/>
	2	Photochemical Reactions, Solid-State Chemistry of Drugs, 2nd edition, 1999, 391-416, SSCI, Inc., West Lafayette, Indiana	<input type="checkbox"/>
	3	Optical Microscopy, USP, 2002, 2040-2042, Vol. 25, Chapter 776, published by the United States Pharmacopoeia	<input type="checkbox"/>
	4	ALBINI, A., et al. Photochemistry of Drugs: An Overview and Practical Problems, Drugs Photochemistry and Photostability, 1998, 1-73, The Royal Society of Chemistry	<input type="checkbox"/>
	5	TONNESEN, H. et al., Photoreactivity of biologically active compounds. XIII. Photostability of mefloquine hydrochloride in the solid state., Drug Stability, 249-253, Vol. 1, No. 4	<input type="checkbox"/>

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6	PRICE, S.L. et al., The computational prediction of pharmaceutical crystal structures and polymorphism, Advanced Drug Delivery Reviews, 2004, 301-319, Vol. 56	<input type="checkbox"/>
7	NORD, K. et al., Photoreactivity of biologically active compounds. XII. Photostability of polymorphic modifications of chloroquine diphosphate, Drug Stability 1997, 243-248, Vol. 1, No. 4	<input type="checkbox"/>
8	MATSUDA, Y. et al., Pharmaceutical evaluation of carbamazepine modifications: comparative study for photostability of carbamazepine polymorphs by using Fourier-transformed reflection-absorption infrared spectroscopy and colorimetric measurement, J. Pharm. Pharmacol., 194, 162-167, Vol. 46	<input type="checkbox"/>
9	MATSUDA, Y. et al., Physicochemical characterization of furosemide modifications, International Journal of Pharmaceutics 1990, 11-26, Vol. 60	<input type="checkbox"/>
10	LIU, X et al., Inclusion of acitretin into cyclodextrins: phase solubility, photostability, and physicochemical characterization, Journal of Pharmaceutical Sciences, 2003, 2449-2457, Vol. 92, No. 12	<input type="checkbox"/>
11	HARRIS, K.D. et al., Probing polymorphism and reactivity in the organic solid state using <sup>13</sup> C NMR spectroscopy: studies of p-formyl-trans-cinnamic acid, Journal of Solid State Chemistry, 1991, 197-205, Vol. 93	<input type="checkbox"/>
12	EL-SHAFEI, A. et al., Semi-empirical molecular orbital methods in the design of organic colorants, AATCC Review, 2001, 23-26, Vol. 1, NO. 12	<input type="checkbox"/>
13	GREENHILL, J.V., Is the photodecomposition of drugs predictable?, Photostability of Drugs and Drug Formulations, [International Meeting on Photostability of drugs], 1st, Oslo, June 1995 (1996), Meeting Date 1995, 83-110, Publisher: Taylor & Francis, London, UK	<input type="checkbox"/>
14	COHEN, M.D. et al., IIE. Influence of crystal structure on reactivity; Structure-Sensitive reactions of organic crystals, Proc. Intern. Symp. Reactivity Solids, 4th Amsterdam, 1981, 556-562,	<input type="checkbox"/>
15	NAKANISHI F. et al., Preparation of p-phenylenediacrylic acid salts and their photoreaction in the solid state, Kenkyu Hokoku-Sen'i Kobunshi Zairyo Kenkyusho, 1982, 39-43, Vol. 133	<input type="checkbox"/>
16	ALBINI, A. et al., Photochemistry of Drugs, Handbook of Photochemistry and Photobiology, 2003, 147-193, American Scientific Publishers, Stevenson Ranch, California	<input type="checkbox"/>



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	17	BOSCA, F. et al., A Laser flash photolysis study on fenofibric acid, Photochemistry and Photobiology, 1999, 853-857, Vol. 70, No. 6	<input type="checkbox"/>
If you wish to add additional non-patent literature document citation information please click the Add button			
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OR

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☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

**SIGNATURE**

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature		Date (YYYY-MM-DD)	8/23/2007
Name/Print	Lisa V. Mueller	Registration Number	38,978

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